

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10577607	
Filing Date	2006-04-27	
First Named Inventor	O'Neill, et al.	
Art Unit	1723	
Examiner Name	TBA	
Attorney Docket Number	50508-1400	

U.S.PATENTS							Remove
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	
	1						

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS							Remove
Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	
	1						

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS							Remove	
Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup>	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T5
	1							<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS							Remove
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.					T5

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10577607
Filing Date	2006-04-27
First Named Inventor	O'Neill, et al.
Art Unit	1723
Examiner Name	TBA
Attorney Docket Number	50508-1400

1	H. FLEISCH, S. BISAZ, "Mechanism of Calcification: Inhibitory Role of Pyrophosphate," NATURE, Sept. 1, 1962, p. 911, Vol. 195, No. 4844, Switzerland. <input checked="" type="checkbox"/>
2	H. FLEISCH, D. SCHIBLER, J. MAERKI, I. FROSSARD; "Inhibition of Aortic Calcification... Polyphosphates," NATURE, Sept. 18, 1965, Vol. 207 No. 5003, Switzerland <input checked="" type="checkbox"/>
3	D. SCHIBLER, R.G.G. Russel, H. FLEISCH, "Inhibition by Pyrophosphate and Polyphosphate... In Rats," Clin. Sci. (1968) 35, pp. 363-372, Davos, Switzerland <input checked="" type="checkbox"/>
4	K.A. LOMASHVILI, S. COBBS, R.A. HENNIGAR, K.I. HARDCastle, W.C. O'NEILL, "Phosphate-Induced Vascular Calcification... Osteopontin," J Am Soc Nephrol 15: 1392-1401, 2004, USA <input type="checkbox"/>
5	K.A. LOMASHVILI, W. KHAWANDI, W.C. O'NEILL, "Reduced Plasma Pyrophosphate Levels in Hemodialysis Patients," J Am Soc Nephrol 16: 2495-2500, 2005, USA <input type="checkbox"/>
6	<input type="checkbox"/>
7	<input type="checkbox"/>
8	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10577607
Filing Date	2006-04-27
First Named Inventor	O'Neill, et al.
Art Unit	1723
Examiner Name	TBA
Attorney Docket Number	50508-1400

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to

any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

- See attached certification statement.
- Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- None

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/CJL/	Date (YYYY-MM-DD)	2007-05-29
Name/Print	Cynthia J. Lee	Registration Number	46033

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Confirmation: to be assigned

O'Neill *et al.*

Art Unit: to be assigned

Serial Number: 10/577,607

Examiner: to be assigned

Filing Date: April 27, 2006

Docket No.: 050508-1400

Title: **DIALYSATES AND METHODS AND SYSTEMS RELATED THERETO****INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

This information disclosure statement is filed in accordance with 37 C.F.R. §§ 1.56, 1.97, and 1.98, and specifically:

- under 37 CFR 1.97(b), or  
(within Three months of filing national application; or date of entry of international application; or before mailing date of first office action on the merits; whichever occurs last)
- under 37 CFR 1.97(c) together with either a:
  - Statement Under 37 C.F.R. 1.97(e), or
  - a \$180.00 fee under 37 CFR 1.17(p), or  
(After the CFR 1.97(b) time period, but before the final office action or notice of allowance, whichever occurs first)
- under 37 CFR 1.97(d) together with a:
  - Statement under 37 CFR 1.97(e), and
  - a \$180.00 petition fee set forth in 37 CFR 1.17(p).  
(Filed after final office action or notice of allowance, whichever occurs first, but before payment of the issue fee)
- Enclosed is a check in the amount of \$ .
- Enclosed is Credit Card Payment Form (PTO-2038) in the amount of \$ .
- Please charge \$ to deposit account .
- At any time during the pendency of this application, please charge any fees required to Deposit Account 20-0778 pursuant to 37 CFR 1.25. The Commissioner is hereby requested to credit any overpayment to Deposit Account No. 20-0778.
- Applicant(s) submit herewith *Form PTO SB/08A-08B-08a - Information Disclosure Statement by Applicant* together with copies (where required) of patents, publications or other information of which applicant(s) are aware, which applicant(s) believe(s) may or may not be material to the examination of this application and for which there may be a duty to disclose in accordance with 37 CFR 1.56. As required by 37 C.F.R. §1.98(a), a legible copy of each document is provided.

A concise explanation of the relevance of foreign language patents, foreign language publications and other foreign language information listed on PTO Form SB/08A-08B-08a, as presently understood by the individual(s) designated in 37 CFR 1.56(c) most knowledgeable about the content is given on the attached sheet, or where a foreign language patent is cited in a search report or other action by a foreign patent office in a counterpart foreign application, an English language version of the search report or action which indicates the degree of relevance found by the foreign office is listed on the form PTO SB/08A-08B-08a and is enclosed herewith.

The following rights are reserved by the Applicant(s): the right to establish the patentability of the claimed invention over any of the listed documents should they be applied as reference, and/or the right to prove that some of these documents may not be prior art, and/or the right to prove that some of these documents may not be enabling for the teachings they purport to offer.

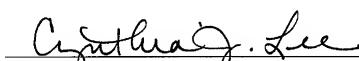
This statement should not be construed as a representation that an exhaustive search has been made, or that information more material to the examination of the present application does not exist. Any statements or identifications regarding the relevance of any portion(s) of cited references should not be construed as a representation that the most relevant portion(s) have been identified, and the absence of such statements or identifications should not be construed as representations that there are no relevant portion(s). The Examiner is specifically requested not to rely solely on the materials submitted herewith. The Examiner is requested to conduct an independent and thorough review of the documents, and to form independent opinions as to their significance.

It is requested that the information disclosed herein be made of record in this application and that the Examiner initial and return a copy of the enclosed PTO SB/08A-08B-08a to indicate the documents have been considered.

Respectfully Submitted,

THOMAS, KAYDEN, HORSTEMEYER  
& RISLEY, L.L.P.

By:

  
Cynthia J. Lee, Reg. No. 46,033

100 Galleria Parkway, N.W.  
Suite 1750  
Atlanta, Georgia 30339-5948  
Phone: (770) 933-9500  
Fax: (770) 951-0933